

AMENDMENT TO COMMITTEE PRINT OF H.R. 1418

OFFERED BY M____. _____

[Committee Print shows text of Amendment in the Nature of a Substitute as favorably forwarded by the Subcommittee on Health on May 17, 2023.]

Add at the end the following:

1 **SEC. 304. REGULATION OF ZOOTECHNICAL ANIMAL FOOD**

2 **SUBSTANCES.**

3 (a) DEFINITION.—Section 201 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 321) is amended by
5 adding at the end the following:

6 “(tt)(1) The term ‘zootechnical animal food sub-
7 stance’ means a substance that—

8 “(A) is added to the food or drinking water of
9 animals;

10 “(B) is intended to—

11 “(i) reduce the presence of foodborne
12 pathogens of human health significance in an
13 animal intended to be used for food;

14 “(ii) affect the structure or function of the
15 body of the animal by altering the animal’s gas-
16 trointestinal microbiome; or

17 “(iii) affect byproducts of the digestive
18 process in an animal; and

1 “(C) achieves its intended effect by acting solely
2 within the gastrointestinal tract of the animal.

3 “(2) Such term does not include a substance that—

4 “(A) is intended for use in the diagnosis, cure,
5 mitigation, treatment, or prevention of disease in an
6 animal;

7 “(B) is a hormone or a precursor to a hormone;

8 “(C) is an active moiety in an animal drug,
9 which, prior to the filing of a petition under section
10 409 was approved under section 512, conditionally
11 approved under section 571, indexed under section
12 572, or for which substantial clinical investigations
13 have been instituted and for which the existence of
14 such investigations has been made public;

15 “(D) is an ionophore; or

16 “(E) is otherwise excluded from the definition
17 based on criteria established by the Secretary
18 through notice and comment rulemaking.

19 “(3) A zootechnical animal food substance shall be
20 deemed to be a food additive within the meaning of section
21 (s) and its introduction into interstate commerce shall be
22 in accordance with a regulation issued under section 409.
23 A zootechnical animal food substance shall not be consid-
24 ered a drug under subsection (g)(1)(C) solely because the

1 substance has an intended effect described in paragraph
2 (1).”.

3 (b) FOOD ADDITIVES.—Section 409 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 348) is amend-
5 ed—

6 (1) in subsection (b)—

7 (A) by redesignating paragraphs (3)
8 through (5) as paragraphs (4) through (6), re-
9 spectively; and

10 (B) by inserting after paragraph (2) the
11 following:

12 “(3) In the case of a zootechnical animal food
13 substance, such petition shall, in addition to any ex-
14 planatory or supporting data, contain—

15 “(A) all relevant data bearing on the effect
16 the zootechnical animal food substance is in-
17 tended to have and the quantity of such sub-
18 stance required to produce the intended effect;
19 and

20 “(B) full reports of investigations made
21 with respect to the intended use of such sub-
22 stance, including full information as to the
23 methods and controls used in conducting such
24 investigations.”;

25 (2) in subsection (c)—

1 (A) by amending subparagraph (A) of
2 paragraph (1) to read as follows:

3 “(A)(i) by order establish a regulation
4 (whether or not in accord with that proposed by
5 the petitioner) prescribing—

6 “(I) with respect to 1 or more
7 proposed uses of the food additive in-
8 volved, the conditions under which
9 such additive may be safely used (in-
10 cluding specifications as to the par-
11 ticular food or classes of food in or on
12 which such additive may be used, the
13 maximum quantity which may be used
14 or permitted to remain in or on such
15 food, the manner in which such addi-
16 tive may be added to or used in or on
17 such food, and any directions or other
18 labeling or packaging requirements
19 for such additive as the Secretary de-
20 termines necessary to assure the safe-
21 ty of such use); and

22 “(II) in the case of a zootechnical
23 animal food substance, the conditions
24 under which such substance may be

1 used to achieve the intended effect;

2 and

3 “(ii) notify the petitioner of such
4 order and the reasons for such action; or”;

5 and

6 (B) in paragraph (3)—

7 (i) in subparagraph (A), by striking “;
8 or” and inserting a semicolon;

9 (ii) in subparagraph (B), by striking
10 the period and inserting “; or”; and

11 (iii) by adding at the end the fol-
12 lowing:

13 “(C) in the case of a zootechnical animal
14 food substance, fails to establish that the pro-
15 posed use of the substance, under the condi-
16 tions of use to be specified in the regulation,
17 will achieve the intended effect.”; and

18 (3) by adding at the end the following:

19 “(1) ZOOTECHNICAL ANIMAL FOOD SUBSTANCES.—
20 The labeling of a zootechnical animal food substance—

21 “(1) shall include the statement: ‘Not for use in
22 the diagnosis, cure, mitigation, treatment, or preven-
23 tion of disease in animals.’; and

24 “(2) may include statements regarding the in-
25 tended effect of the substance on the structure or

1 function of the body of animals, as set forth in sec-
2 tion 201(tt)(1).”.

3 (c) MISBRANDED FOOD.—Section 403 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amend-
5 ed by adding at the end the following:

6 “(z) If it is or it bears or contains a zootechnical ani-
7 mal food substance and the labeling of the food does not
8 include the statement required by section 409(l)(1).”.

9 (d) RULE OF CONSTRUCTION.—Nothing in this sec-
10 tion, or the amendments made by this section, shall be
11 construed to authorize the Secretary of Health and
12 Human Services to require the use of any zootechnical
13 food substance or food additive (as those terms are defined
14 in section 201 of the Federal Food, Drug, and Cosmetic
15 Act, as amended by subsection (a)).

